

# Categorical Exclusion under 21 CFR 25.31(c) - Seraclone Blood Grouping Reagent Anti-S (Monoclonal)

To: Administrative Bundled File Biotest AG (LIC #1702):

Products for use on the Tango Automated Blood Group Analyzer Products for use on the Tango Automated Blood Group Analyzer

(STN)	Biological Products	Cell Line(s)	Strip Proprietary Name
BL 125097/10	Blood Grouping Reagent, Anti-D (Monoclonal)(IgM) (Formulated for Automated Testing)	BS226	Component of Erytype S Rh+K
BL 125206/0	Blood Grouping Reagent, Anti-D (Monoclonal)(IgM) (Formulated for Automated Testing)	BS232	Component of Erytype S Rh+K
BL 125202/0	Blood Grouping Reagent, Anti-C (Monoclonal) (Formulated for Automated Testing)	MS24/P3x25513G8	Component of Erytype S Rh+K
BL 125205/0	Blood Grouping Reagent, Anti-E (Monoclonal) (Formulated for Automated Testing)	MS260/MS12	Component of Erytype S Rh+K
BL 125203/0	Blood Grouping Reagent, Anti-c (Monoclonal) (Formulated for Automated Testing)	MS33	Component of Erytype S Rh+K
BL 125204/0	Blood Grouping Reagent, Anti-e (Monoclonal) (Formulated for Automated Testing)	MS16/MS21/ MS63	Component of Erytype S Rh+K
BL 125204/0	Blood Grouping Reagent, Anti-K (Monoclonal) (Formulated for Automated Testing)	MS56	Component of Erytype S Rh+K

NOTE- Erytype S are strip wells (eight wells per strip) containing: Anti-D, Anti-D, Anti-C, Anti-c, Anti-E, Anti-e and Anti-K+ Neg Cont

	Reagent Red Blood Cells For Use in Automated Systems	Cell Line(s)
BL 125208/0	Erytypecell A 1 and B	N/A
	Biotestcell Pool; Biotestcell 1, 2; Biotestcell 3	N/A
	Biotestcell I8; Biotestcell I11	N/A
BL 125218/0	Blood Grouping Reagent Anti-D (Monoclonal) (IgG Blend)	BS221/H4111B7

Seraclone- Liquid BGR for manual tube testing :

(STN)	Biological Products	Cell Line(s)
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<b>(STN)</b>	<b>Biological Products</b>	<b>Cell Line(s)</b>
BL 125222/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)	BS226
BL 125223/0	Blood Grouping Reagent, Anti-D (Monoclonal Blend)	BS232/BS221/H4111B7
BL 125226/0	Blood Grouping Reagent, Anti-C (Monoclonal)	MS24
BL 125227/0	Blood Grouping Reagent, Anti-c (Monoclonal)	MS33
BL 125228/0	Blood Grouping Reagent, Anti-E (Monoclonal)	MS12/MS260
BL 125229/0	Blood Grouping Reagent, Anti-e (Monoclonal)	MS16/MS21/MS63
BL 125212/0	Blood Grouping Reagent, Anti-Fy a (Monoclonal)	GD-FYA-02
BL 125214/0	Blood Grouping Reagent, Anti-s (Monoclonal)	P3YAN3
BL 125216/0	Blood Grouping Reagent, Anti-S (Monoclonal)	MS94
BL 125217/0	Blood Grouping Reagent, Anti-Jk b (Monoclonal)	MS8
BL 125231/0	Blood Grouping Reagent, Anti-Jk a (Monoclonal)	MS15
BL 125219/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal)	A003
BL 125220/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal)	B005
BL 125221/0	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)	BS63 and BS85
BL 125224/0	Blood Grouping Reagent, Anti-M (Murine Monoclonal)	BS57
BL 125225/0	Blood Grouping Reagent, Anti-N (Murine Monoclonal)	BS41
BL 125230/0	Blood Grouping Reagent, Anti-K (Monoclonal)	MS56
BL 125232/0	Blood Grouping Reagent, Anti-k (Murine Monoclonal)	Lk1
BL 125233/0	Blood Grouping Reagent, Anti-Le a (Murine Monoclonal)	LEA2
BL 125213/0	Blood Grouping Reagent, Anti- P 1 (Murine Monoclonal)	650

#### Other Reagents for Manual Tubes Testing

<b>(STN)</b>	<b>Anti-Human Globulin</b>	<b>Cell Line(s)</b>
BL 125242/0	Anti-Human Globulin (Rabbit/Murine Monoclonal)	BRIC-8
BL 125215/0	Anti-Human Globulin	N/A
<b>BL125098/8</b>	Anti-Human Globulin (Formulated for Automated Testing)	<b>N/A</b>
<b>(STN)</b>	<b>Reagent Red Blood Cells</b>	<b>Cell Line(s)</b>
	Biotestcell A 1 and B	N/A
	Biotestcell A 2	N/A
BL 125207/0	Biotestcell Pool; Biotestcell 1, 2; Biotestcell 3	N/A
	Biotestcell I8; Biotestcell I11	N/A

From: Marion Michaelis HFM-676

Subject: Categorical Exclusion under 21 CFR 25.31(c)

Date: July 30, 2008

I have reviewed pertinent sections of the Biologics License Application's (STN) from Biotest AG (License #1702), for manufacturing multiple new Blood Grouping Reagents, Anti-Human Globulin, and Reagent Red Blood Cells (specified above), and find that the request for a categorical exclusion from an environmental assessment under 21 CFR 25.31(c) is justified because the above mentioned product's fall into the category of

substances that occur naturally in the environment and action would not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

07/30/08

Marion Michaelis  
Committee Facility/CMC Reviewer

Concurrence:

John A. Eltermann, Jr., R.Ph., M.S.  
Director  
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